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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/823,294	VOORHEES ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23,32-51,53-58,62-70,73,84-86 and 95-99* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,14,15,18-23,32,34,37-39,46-50,84,85 and 96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 April 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/19/04 4/20/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 8-13,16,17,33,35,36,40-45,51,53-58,62-70,73,86,95 and 97-99.

DETAILED ACTION

1. Claims 1-23, 32-51, 53-58, 62-70, 73, 84-86, 95-99 are pending in the application.

Election/Restrictions

2. Applicant's election of Group I, and species wherein progeny phage (not associated biological substances) are detected, infected microorganisms are lysed through phage multiplication, detection involves the use of a flow strip, the bacteriophage are modified to over-express a detectable biomarker in the reply filed on June 14, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 8-13, 16, 17, 33, 35, 36, 40-45, 51, 53-58, 62-70, 73, 86, 95, and 97-99 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 14, 2007.

It is noted that claim 13 is drawn to a method involving the use of a laser for detection. The limitation of this claim was clearly indicated to fall within the scope of a non-elected species. See, election requirement of May 2007, page 5. Moreover, those linking claims limited to non-elected species have also been withdrawn from examination. Moreover, because claim 51 requires the dissociation of phage in step b/, but prohibits the destruction of the phage prior to the incubation of the phage, this claim reads only on methods involving the dissociation of phage such that phage associated substances may be detected. Such embodiments represent non-elected

species. Claim 51 is therefore withdrawn. Claim 53 and its dependent claims are drawn to the detection of a specific substance associated with the progeny phage, and therefore represent non-elected species of the invention.

4. Claims 1-7, 14, 15, 18-23, 32, 34, 37-39, 46-50, 84, 85, and 96 are under consideration.

Information Disclosure Statement

5. The information disclosure statements (IDS) submitted on July 19, 2004 and on April 20, 2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Drawings

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description:

there is no reference in the specification to

item 26 of Figure 1,

item 4 of Figure 3C ,

item 93 of Figure 6,

item 320 of Figure 23 (page 30 refers instead to item 331, found in Figure 24, and which item is not described in the description of Figure 24 on pages 30-31).

In addition, there are multiple

items 262 in Figure 19, one of which does not appear to correspond to the description on page 28;

items 335 in Figure 24, one of which appears to correspond to item 355 described on page 31.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 18-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims further limit independent claims describing a method of detecting a target microorganism comprising (a) combining a sample with a bacteriophage capable of infecting the target microorganism, (b) providing conditions that permit the phage to infect and multiple to create a detectable amount of phage/phage capsid, and (c) assaying the sample to detect the presence of the phage/phage capsid protein wherein the presence of absence of the phage/protein acts as an indicator of the presence of the microorganism. Claims 18, 21, and 57

require that the step of providing comprises dissociation said bacteriophage, and the remaining claims further require the use of a dissociating agent.

The claims are rejected because it is not clear what the scope of the claims is. In particular, it is not clear if the dissociation occurs before or after the target bacteria are lysed. If before, the claims read on the elected species of the claims, and permit the detection of whole progeny bacteriophage. If the latter, then the method involves only the detection of bacteriophage capsid protein that is dissociated from the remainder of the compounds forming the phage, and would not read on the elected species.

It is noted that the sole example of such a dissociation provided in the application is an example where the phage are dissociated after the target microorganisms have been infected and lysed. See e.g., pages 21-22 (describing the method of Figure 6) and 25 (lines 10-12). Thus, it is not clear if the Applicant intended that the dissociation occur at a specific point during step (b), or specifically after progeny phage had been released from the target microorganism. As claims are read broadly before the Office, the indicated claims are treated as reading on methods wherein the dissociating agent may be added at any point in step (b).

9. Claims 37-39, 46-50, 84, and 85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejected claims read on a method for the detection of a target microorganism in a sample through detection of the presence or absence of bacteriophage that have infected and multiplied in the target microorganism. The claims describe a method including the steps of (a) combining a sample with bacteriophage capable of infecting the target

organism, (b) culturing the exposed sample such that the phage infect and multiple in the target organism if present "to create a detectable amount of" the bacteriophage, and (c) assaying the sample for the phage.

The scope of what is being claimed in unclear. It is noted that claim 1 of the application discloses a similar method. However, while claim 1 requires that the phage infect and multiple in the target organism, if present, that claim also requires that the sample is combined with "an amount of parent bacteriophage capable of infecting said target organism..., said amount of parent bacteriophage being less than the threshold amount of bacteriophage capable of being detected." Thus, claim 1 specifically requires both that the sample to be tested is combined with an undetectable amount of phage and that infection of the target organism results in the production of a detectable amount of phage, such that presence or absence of a detectable amount of the phage is an indicator of the presence of the target organism.

In contrast, while the rejected claims require that infection of the target organism results in the production of a detectable amount of phage, the claim is silent as to the amount of parent phage combined with the sample. Moreover, the present application provides alternative means for distinguishing between parent and progeny phage.. See e.g., pages 18-19. Thus, it is not clear if the inclusion of the language "to create a detectable amount of" phage in claim 46 is intended to require that only an undetectable amount of parent phage was added to the sample, or if the claim language was intended to indicate that a detectable amount of progeny phage was produced independent of the amount of parent phage added to the sample.

Claim Rejections - 35 USC § 102 and 103

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 43-48 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Takahashi et al. (WO 98/08944- the specification of which is translated in U.S. 6,322,783). These claims read on a method for the detection of a target bacteria in a sample comprising (a) combining the sample with a target bacteriophage capable of infecting the target bacterium, (b) incubating the sample with the phage so as to permit the phage to infect and replicate in the target bacterium without inactivating the extracellular phage (i.e. phage that does not infect the target bacterium), and (c) assaying the sample to detect the presence or absence of bacteriophage to determine the presence or absence of the target microorganism.

Takahashi teaches a method for screening for a target microorganism according to the claimed method. See e.g., U.S. Patent 6,3222,783, column 10, lines 10-35. This method involves combining a lytic phage with a sample to be tested for the presence of a target bacterium, and incubating the sample to permit the phage to infect and replicate in the target bacteria if present.

If the target bacteria is present, the phage will be detected by the formation of plaques on the plated sample. If the bacteria is not present, no phage will be detected through the plaque assay. Because the method involves the use of lytic phage and the use of a plaque assay, the method inherently requires that the phage infect and cause the lysis of the target bacteria if present.

13. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi (supra) in view of U.S. 5,789,174. This claim reads on the method of claim 43 as described above, further requiring the use of a reference indicating the assay result if no target bacterium are present. This claim is rejected as it is known in the art to use negative controls as a measure for the accuracy of bacterial detection assays. See e.g., U.S. 5,789,174, column 7, lines 13-30. In particular, this reference demonstrates the use of negative controls in assays for the detection of bacterial pathogens. While the reference uses an alternative means for detecting the pathogens from that disclosed in the Takahashi reference, it would nonetheless be obvious to those of ordinary skill in the art to use such negative controls to determine the accuracy and specificity of the phage-based assay in Takahashi. There would have been a reasonable expectation of success in the use of such controls as negative controls are generally accepted in the art. The combined teachings of these references therefore render the claimed methods obvious.

14. Claims 1-3, 6, 14, 15, 18-23, 32, and 96 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rees et al., (WO 92/02633). These claims read on a method for the detection of a target microorganism (esp. a bacteria) comprising (a) combining a sample with an amount of bacteriophage capable of

infecting the target microorganism that is below the threshold amount capable of being detected, (b) providing conditions that permit the phage to infect and multiple to create a detectable amount of phage, and (c) assaying the sample to detect the presence of the phage wherein the presence of absence of the protein acts as an indicator of the presence of the microorganism. Claims 2 and 96 require that the method is used to detect the presence of a bacterium (it is noted that the specification defines bacteriophage as a virus capable of infecting any microorganism- page 11, lines 29-31). Claim 3 requires that the conditions provided cause the phage to multiple sufficiently to burst the target bacterium. Claim 6 requires the use on antibody to detect the phage. Claims 14 and 15 require that the phage lyses the target microorganism by causing it to burst (i.e. phage induced lysis). Claims 18-23 require that step (b) includes a step of dissociation of said bacteriophage, and the use of a dissociation agent, such as an acid, to do so. Claim 32 requires that us of a genetically modified phage.

Rees teaches a method for the detection of target bacterium in a sample comprising the use of phage. Abstract. The method involves the addition of phage to a sample to infect the target bacteria, amplifying phage in the sample (i.e. permitting them to replicate in the target bacteria), and detecting the resulting phage. Abstract. The reference indicates that the progeny phage may be detected through the use of an immunoassay (pages 6-7), or through the use of a plaque assay (which requires that the infected bacteria are lysed through phage induced bursting). The reference also teaches the dissociation of phage after infection but before lysis and assaying (i.e. during step (b) of the claimed methods), including embodiments wherein the dissociation is through use of an acid. Page 6, lines 10-13, and page 8, lines 16-18. The reference also teaches that the phage may be genetically modified (i.e. that a mutant version of the phage may be used).

See e.g., page 16, lines 21-29. Thus, the reference clearly teaches all of the limitations of the claimed methods, with the possible exception of the requirement that the sample be contacted with an amount of phage below a threshold detection amount.

With reference to the requirement that the sample be contacted with an amount of phage below a threshold detection amount, it is noted that the reference indicates that "The number of bacteriophages protected and able to replicate and emerge may be sufficient to be detected directly." Page 6, lines 29-31. Thus, the reference indicates that the sample may be contacted with an amount of bacteriophage below a threshold detection amount. The reference also indicates that the resulting progeny phage may also be below the detection amount such that further amplification is required, or may be directly detectable (i.e. at or above the threshold detection amount). Pages 6-7. In the alternative, even if the reference does not specifically teach that the sample may be detected through contacting the cells with an amount of phage below the threshold for detection, such would have been obvious to those of ordinary skill in the art in view of the teachings of the reference indicating that progeny phage from infected cells may be further amplified. This is because, as the reference teaches that the progeny phage may be amplified, those of ordinary skill in the art would have recognized that the cells need not be contacted with sufficient numbers of phage to ensure that the initial levels of progeny phage would be detectable. Rather, the presence of additional amplification would have enabled those of ordinary skill in the art to use smaller amounts of phage to infect the target cells, with the expectation that, if target bacteria were present, later amplification of progeny phage would bring the levels of such to a detectable amount.

The teachings of the reference therefore either anticipate, or render obvious, the claimed methods.

15. Claims 4, 5, 7, 37-39, 84, and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rees as applied against claims 1-3, 6, 14, 15, 18-23, 32, and 96 above, and further in view of Rittenburg et al., (U.S. 5,710,005). The method of the previously rejected claims has been described above. Claim 7 requires that the sample is poured into a container comprising the phage. Claims 4, 5, and 37-39 read on the method of claim 1, wherein the method involves the detection of the progeny phage through use of a lateral-flow strip, and of colored beads Claims 84 and 85 require the use of a substrate, a portion of which changes color if the phage is present in the sample when applied to the substrate.

The teachings of Rees have been described in part above. While the reference teaches adding the phage to a sample (see e.g., abstract), it would have been equally obvious to those of ordinary skill in the art to add the sample to a composition comprising the phage instead. This is because those of ordinary skill in the art would have recognized the two alternative means for bringing the sample into contact with the phage as functional equivalents. As was also described above, Rees indicates that the resulting progeny phage may be detected through the use of an immunoassay. However, the reference does not teach or suggest the use of a lateral flow strip, the use of colored beads, or embodiments wherein the color of a substrate changes if the progeny phage is present.

Rittenburg teaches a method for the detection of an analyte, including viral antigens, through the use of a lateral flow strip based assay. See e.g., claims 1 and 5. The reference teaches that the analyte may be detected through the use of a binding partner to the analyte, such as an

antibody, conjugated to a signaling substance, such as a latex bead. Claims 13 and 14. The reference also specifically indicates that the latex bead may be a colored latex bead. Column 3, line 67. The reference teaches that presence of the analyte is determined by through a detectable signal produced in the test zone in the presence of the analyte. Because the reference teaches that colored beads represent an embodiment of a signaling substance, a change of color of the test zone corresponding to the presence of the beads would represent such a detectable signal.

16. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rees as applied to claims 1-3, 6, 14, 15, 18-23, 32, and 96 above, and further in view of Ulitzur et al. (EP 0 168 933) and of Bittner et al. (EP 0 439 354- of record in the July 2004 IDS). This claim is directed to the method of claim 1, wherein the bacteriophage is modified to "over-express a detectable biomarker." It is noted that there has been no definition of the term biomarker in the application. Thus, the term is read broadly as being any biological marker useful for indicating that progeny phage are produced.

The teachings of Rees have also been described in part above. The reference also indicates that the production of progeny phage may be detected through the use of a reporter bacteria that expresses a reporter protein (i.e. a biomarker). However, while this reference teaches the use of phages to detect target bacteria, and teaches the use of genetically modified phages, and the use of biomarkers, it does not teach or suggest the use of the genetically modified phages that over-express a biomarker of claim 34.

Ulitzur also teaches the use of phage for the detection of a target bacteria. Abstract. In particular, the reference teaches the use of phages that, upon infection of the target bacteria,

express a protein recombinantly encoded by the phage genome. Claims 1-5. It is noted that the teachings in the art indicate that, due to the way in which phage replicate, and in which proteins are translated from the phage DNA, proteins encoded by phages are over-expressed (amplified). See e.g., Bittner, page 4, lines 48-60. Thus, by teaching the expression of the reporter proteins from phages, the Ulitzur reference inherently teaches the over-expression of a biomarker.

As can be seen from these teachings, each of Rees and Ulitzur teach the use of a phage for the detection of a target bacteria. The references vary in the means for the detection of the target bacteria, with Rees using the reporter bacterium that express a biomarker upon infection of phage replicated in the target bacteria, and Ulitzur teaching the detection of a biomarker directly expressed from the phage in the target bacteria upon infection by the phage. It would have been obvious to those of ordinary skill in the art to substitute the phage of Ulitzur for the phage of Rees in the method described by Rees so as to avoid the need for a reporter bacteria, and because those of ordinary skill in the art would have recognized that each of these methods represented a functional equivalent means for the detection of phage infection of the target bacteria, and thus the presence of the target bacteria. There would also have been a reasonable expectation of success in the combination as the phage of Ulitzur are described as useful for the detection of target bacterial hosts. The combined teachings of the references therefore render the claimed method obvious.

Double Patenting

17. Applicant is advised that should claim 2 be found allowable, claim 96 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application

are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-3, 6, 7, 14, 15, and 96 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8 of U.S. Patent No. 7,166,425. Although the conflicting claims are not identical, they are not patentably distinct from each other. As indicated above, the presently rejected claims read on a method for the detection of a microorganism, including bacteria (claims 2 and 96), through the use of phages. The methods include steps of providing a parent phage to the sample, including where the parent phage is provided in an undetectable amount; permitting the phage to infect and multiple in the target bacterium, and detecting the resulting progeny phage in the sample. Such a method is disclosed

in the patented claims. Claims 6 and 84 respectively require the use of an antibody in the detection method, or the use of a test strip that changes color in the presence of the progeny phage. The patent claims teach the use of immunoassays and chromatographic assays for the detection of progeny phages, and therefore render obvious the present claims. Claim 7 requires that the sample is added to the parent phage. The patent claims read generally on the commingling of the sample and the phage. From this, it would have been obvious to those of ordinary skill in the art to add the sample to a phage composition, or vice versa. Claims 3, 14, and 15 require that the phage cause the bacteria to burst. While the claims of the patent are silent as to this, the specification of the patent indicates that this is the means by which the phage are released from the target host cells. See, column 2, lines 56-60. Thus, the patent claims implicitly read on the method of these claims.

20. Claims 18-23, and 32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8 of U.S. Patent No. 7,166,425 in view of Rees et al. (supra). The rejected claims have been described above, as have the patent claims. The patent claims do not teach or suggest the dissociation of phages, or the use of a genetically modified phage.

Like the patented claims, Rees also teaches a method for the detection of bacteria through the use of bacteriophages. Moreover, as was described above, the reference teaches, or renders obvious, contacting the sample to be tested with an undetectable amount of phage. Thus, the reference teaches a similar method to that in the patented claims. The reference indicates that in the performance of the method, phage that do not infect target bacteria may be dissociated

through the use of a dissociating agent, such as an acid. Page 6, lines 10-13, and page 8, lines 16-18. The reference also teaches that the phage may be genetically modified (i.e. that a mutant version of the phage may be used). See e.g., page 16, lines 21-29. In view of these teachings, it would have been obvious to those of ordinary skill in the art to combine the teachings of Rees with those of the patent claims so as to arrive at the presently claimed inventions. The motivation for the combination would be the teachings in Rees to inactivate the extracellular phage in the sample, and the suggest the use of phages that have been mutated to be more sensitive to inactivation. The combined teachings of the reference and the patent claims therefore render the present claims obvious.

21. Claims 4, 5, 37-39, and 85 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8 of U.S. Patent No. 7,166,425 in view of Rittenburg et al. (supra). These claims have been described above. The patent claims have also been described above. These claims do not teach or suggest the use of a lateral flow strip, or the use of colored beads, for the detection of the progeny phage.

However, as was described above, Rittenburg teaches the use of immunoassays comprising the use of a lateral flow strip and of colored beads for the detection of analytes, including viral antigens. As the method of the patented claims suggests the use of immunoassays for the detection of the phages, and as Rittenburg teaches that the lateral flow based immunoassays disclosed therein may be used for the detection of viral antigens, it would have been obvious to those of ordinary skill in the art to have used such assays as the immunoassay

for the detection of progeny phages suggested by the patent claims. The presently rejected claims therefore represent obvious embodiments of the patented claims.

22. Claims 1-3, 7, 14, 15, 37-39, 84, 85, and 96 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-6, 8-10 of copending Application No. 11/698,673. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims represent a species of the copending claims. See e.g., claims 6, 8, and 9 of the copending application, specifying that the generic claim 1 of that application is limited to embodiments wherein the parent phage is added in an undetectable amount (as in claim 1) or wherein the progeny phage are detected through use of a colorimetric assay (as required by present claim 84), or of a lateral flow immunoassay (such as is described in present claim 37).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

23. No claims are allowed.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Z. Lucas/
Patent Examiner, AU 1648